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November 10, 2020

**VIA ECF**
The Honorable Gregory H. Woods
Daniel Patrick Moynihan United States Courthouse
500 Pearl Street
New York, New York 10007-1312

Re: *Skiadas v. Acer Therapeutics Inc., et al.*, Case No. 1:19-cv-06137-GHW

Dear Judge Woods:

We write to inform the Court that Lead Plaintiff Skiadas ("Plaintiff") intends to move to amend the Second Amended Complaint (ECF No. 43) based on new information contained in Defendants' pre-mediation document production to Plaintiff. Last Friday, we sent a draft of the Third Amended Complaint to Defendants so that they could begin to assess their positions on Plaintiff's motion to amend and whether the Court should seal portions of the potential Third Amended Complaint because it contains confidential information.

**Defendants Produced Documents Showing That Defendants' Statements About What the "FDA Agreed" to were False and Misleading for Additional Reasons and Numerous Other Statements in the Class Period Were False and Misleading.**

The Court issued an opinion and order mostly denying Defendants' motion to dismiss the Second Amended Complaint on June 16, 2020 (ECF No. 54) and an opinion and order denying Defendants' motion to reconsider that opinion on July 21, 2020 (ECF No. 63.) The Court entered a scheduling order on August 17, 2020. (ECF No. 67.)

On September 14, 2020, ahead of a October 7, 2020 mediation conducted by the Parties, Defendants produced more than 36,000 pages of documents. Defendants' production included the official minutes that the FDA[1] prepared for the meetings concerning EDSIVO that it held with Acer and other FDA correspondence with Acer. Those documents show additional reasons why Defendants' statements that "the FDA agreed that additional clinical development is not needed" and "the FDA agreed that an additional clinical trial is not likely needed" for EDSIVO were false and misleading and also made clear that numerous other statements that Defendants made during the class period were false and misleading.

[redacted]

[1] This letter adopts the definitions from the Second Amended Complaint.

[redacted]

Defendants also produced briefing packages that Acer submitted to the FDA in preparation for meetings it had with the Agency on June 14, 2018 and June 28, 2018. Both of those briefing packages contained a description of what occurred at Acer's September 30, 2015 meeting with Acer. In stark contrast to Acer's statements in their public filings, [redacted] Accordingly, it is irrefutable that Acer never had an agreement with the FDA that "additional clinical development is not needed" for EDVISO about ***approval or submission*** of EDSIVO's NDA.

[redacted] the FDA repeatedly warned Defendants that the Ong Trial had serious flaws that made it insufficient to show that EDSIVO was effective against vEDS and its results not statistically significant. [redacted] This was an especially serious problem because the Ong Trial was terminated early based on these improperly conducted interim analyses.

Defendants failed to disclose any of the FDA's warnings about the flaws in the Ong Trial, which the Agency communicated to Defendants repeatedly over a period of more than two years before it rejected EDSIVO's NDA for those same reasons. Instead, Defendants made numerous positive statements about the Ong Trial and EDSIVO's prospects for approval based on it.

**Plaintiff's Anticipated Motion to Amend is Proper.**

"Rule 15…directs the Court to freely give leave [to amend] when justice so requires." *Int'l Techs. Mktg., Inc. v. Verint Sys., Ltd*., No. 1:15-CV-2457-GHW, 2019 WL 1245013, at *3 (S.D.N.Y. Mar. 18, 2019) (Woods, J.) (internal quotations marks omitted). Where, as here, "'a scheduling order governs amendments to the complaint, the lenient standard under Rule 15(a) ... must be balanced against the requirement under Rule 16(b) that the Court's scheduling order shall not be modified except upon a showing of good cause.'" *Id.* (quoting *Holmes v. Grubman*, 568 F.3d 329, 334-35 (2d Cir. 2009).) When determining whether good cause exists, courts consider the diligence of the moving party and whether the proposed amendment rests on information that the party knew, or

should have known, prior to the deadline. *Id.*

Here, Plaintiff was not aware of the facts necessary to amend the Second Amended Complaint by the scheduling order's September 16, 2020 deadline to move to amend. The documents prompting amendment were contained in 36,000 pages of documents that Defendants produced only two days before on September 14, 2020. After receiving Defendants' production, Plaintiff diligently worked to identify the important documents and consulted with an expert to analyze them since they are highly technical. Additionally, Plaintiff had to re-review all of Plaintiff's public statements to determine if the new information rendered those statements false or misleading. Accordingly, Plaintiff has shown the necessary diligence for a showing of good cause. *See, e.g. Olaf Soot Design, LLC v. Daktronics, Inc.*, 299 F. Supp. 3d 395, 399 (S.D.N.Y. 2017) (holding that moving to amend "within a few months after receiving and reviewing" relevant documents was sufficiently diligent); *City of Almaty, Kazakhstan v. Ablyazov*, No. 115CV05345AJNKHP, 2019 WL 2324587, at *2 (S.D.N.Y. May 29, 2019) ("Courts in this District have found that a time period of less than three months [after receiving new information] satisfies the diligence standard under Rule 16").

When determining whether to grant leave to amend under Rule 16, courts also consider whether granting leave would prejudice Defendants and may permit amendment even in the absence of diligence where it does not prejudice them. *See Olaf Soot Design*, 299 F. Supp. 3d at 399; *Int'l Techs. Mktg., Inc.*, 2019 WL 1245013, at *5. Here, there is no prejudice at all to Defendants. Since discovery was stayed while Defendants moved to dismiss the Second Amended Complaint, the only discovery that has occurred in this case is Defendants' pre-mediation production. Since Plaintiff agreed to Defendants request to delay serving their responses and objections to Plaintiff's First Request for Production until after the scheduled mediation, Defendants did not serve their responses and objections until October 23, 2020. Furthermore, Plaintiff does not believe that his amendment is likely to alter the discovery necessary in this case. Accordingly, Plaintiff does not anticipate that granting Plaintiff leave to amend will make it necessary for the Court to extend the discovery deadlines.

Lastly, the new information [redacted] — that the FDA warned Defendants for years that the Ong Trial was flawed and there was a significant risk it would not approve EDSIVO — is something Plaintiff pled had likely occurred in the Second Amended Complaint, but Defendants vehemently denied. Defendants went as far as to say that Plaintiff's contention that Defendants would move forward with their NDA even though the FDA warned them about serious flaws in the Ong Trial was illogical and undermined Plaintiff's theory of the case. Given that Plaintiff's contention turned out to be true, it is in the interests of justice to allow Plaintiff to amend the complaint to reflect that fact.

Respectfully submitted,
/s/ *Laurence M. Rosen*



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